PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/64 — A1

(11) International Publication Number: WO 96/19944

(43) International Publication Date: 4 July 1996 (04.07.96)

(21) International Application Number: PCT/IT95/00225

(22) International Filing Date: 22 December 1995 (22.12.95)

(30) Priority Data:
MI94A002615 23 December 1994 (23.12.94) IT

(71)(72) Applicants and Inventors: DANIELI, Giorgio, S. [IT/IT]; Viale Filippetti 28 A, I-20122 Milano (IT). DANIELI, Guido, A. [IT/IT]; Dipartimento di Meccanica, Università della Calabria, I-87030 Arcavacata di Rende (IT).

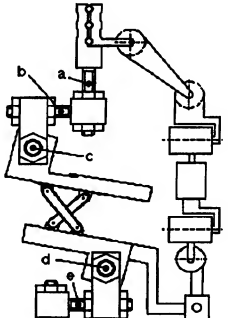
(81) Designated States: US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: ARTICULATION SUPPORT DEVICE

(57) Abstract

Purpose of the system the determination of the correct position of an external structure that, bridging between the bone structures of a physiological articulation, should allow relative motion between the parts without contact nor load, thus allowing healing of an unloaded but working articulation. The system is composed by two fundamental elements, a measuring device allowing the continuous recording of six parameters fully describing the relative motion between its extremes, and an articulation fixator, both supplied at each end by reference slots. In particular the measuring device supplies a computer, equipped with dedicated soft/hardware, the co-ordinates of any point connected to the last member of the kinematic chain of the measuring device with respect to the first member of said chain. The fixator is made in three portions, each bearing six degrees of freedom between its extremes. The end portions of the fixator have to be set to a static configuration, in order to allow properly placing the mechanism used to reproduce the patient's geometry (the central portion of the fixator), with respect to the pins inserted into the patient's bones. Setting of the various degrees of freedom of the system is guided by a computer, while the seventeenth is left to the doctor to centre the articulation supporting device with respect to the articulation itself, and the last coincides with the degree of motion left to the patient. As alternative to the eighteen degrees of freedom fixator, a passive device presenting six degrees of freedom could be used. Such structure, once regulated with the help of the computer, will be used to allow blocking the real fixator in the configuration required by the patient. As further alternative, a mounting robot directly connected to the computer could be used, in order to physically determine the relative position between the fixator member connected to the patient's bone, and the frame or the rod of the mechanism that best fits patient's motion.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	**GB**	United Kingdom	**MW**	Malawi
AT	Austria	**GE**	Georgia	**MX**	Mexico
AU	Australia	**GN**	Guinea	**NE**	Niger
BB	Barbados	**GR**	Greece	**NL**	Netherlands
BE	Belgium	**HU**	Hungary	**NO**	Norway
BF	Burkina Faso	**IE**	Ireland	**NZ**	New Zealand
BG	Bulgaria	**IT**	Italy	**PL**	Poland
BJ	Benin	**JP**	Japan	**PT**	Portugal
BR	Brazil	**KE**	Kenya	**RO**	Romania
BY	Belarus	**KG**	Kyrgystan	**RU**	Russian Federation
CA	Canada	**KP**	Democratic People's Republic of Korea	**SD**	Sudan
CF	Central African Republic			**SE**	Sweden
CG	Congo	**KR**	Republic of Korea	**SG**	Singapore
CH	Switzerland	**KZ**	Kazakhstan	**SI**	Slovenia
CI	Côte d'Ivoire	**LI**	Liechtenstein	**SK**	Slovakia
CM	Cameroon	**LK**	Sri Lanka	**SN**	Senegal
CN	China	**LR**	Liberia	**SZ**	Swaziland
CS	Czechoslovakia	**LT**	Lithuania	**TD**	Chad
CZ	Czech Republic	**LU**	Luxembourg	**TG**	Togo
DE	Germany	**LV**	Latvia	**TJ**	Tajikistan
DK	Denmark	**MC**	Monaco	**TT**	Trinidad and Tobago
EE	Estonia	**MD**	Republic of Moldova	**UA**	Ukraine
ES	Spain	**MG**	Madagascar	**UG**	Uganda
FI	Finland	**ML**	Mali	**US**	United States of America
FR	France	**MN**	Mongolia	**UZ**	Uzbekistan
GA	Gabon	**MR**	Mauritania	**VN**	Viet Nam

Description

ARTICULATION SUPPORT DEVICE

Technical Field

In case of articulation's trauma, the usual procedure is to block the articulations till healing. This may cause a permanent articulation damage and, in the best condition, a long period of rehabilitation. Alternatively, donjoys or elements of plaster of Paris connected by hinges may be used. The present invention deals with a system able to allow motion of physiological articulations in absence of load, being the weight supported by an external device, connected through pins to the patient's bone structure.

Background Art

Currently the task of supporting a damaged articulation when motion is to be permitted is performed by donjoys or by the aforementioned plaster of Paris elements. These however cannot fully support the articulation because they are not connected to the bone structure. On the other hand external articulation fixators that are not guided during calibration by a computer may cause more problems than they solve.

Disclosure of Invention

In order to solve the problem of supporting the weight while allowing at least one degree of motion, a system is needed in which it is first possible to measure the individual patient's articulation geometry, rigidly connecting the proximal and the distal bones facing the articulation, with a measuring device, able to supply a computer the instantaneous values of six parameters used to fully describe the relative motion between its extremes.

Thus, in the case of the knee, pins are inserted both in the femur and tibia. The first member of the measuring device is connected to the femoral pins, while the last is clamped to the tibia pins, and then the knee is articulated while proceeding with the measurement.

It is obvious that in the case of an articulation damaged by a trauma, first the doctor should operate the patient to reconstruct the articulation, then, he should move the patient's articulation allowing via the measuring device to detect the correct patient's geometry.

Then the mechanism that best fits the individual patient, never allowing compression of the articulation to be healed, is to be determined via dedicated software, together with its position with respect to the pins inserted by the doctor into the patient's skeletal structure.

As a third step the mechanism determined as suitable for the patient, should be correctly positioned, placing its frame at the right place with respect to the proximal pins, and similarly its rod, with respect to the distal ones.

To this end each of the two portions of the fixator joining the bone to the articulating mechanism have to be supplied with six degrees of freedom between the extremes. In between, in the case of a knee, a four bar linkage may be inserted whose geometry is fixed by the length of the four bars and by the initial and final angle between the frame (the proximal part of the fixator) and the first crank linking to the rod. In other cases, a simple hinge, but correctly placed, may be sufficient.

The adjustment of the fixator is then performed by comparing, with the help of the measuring device, the recorded individual motion with the fixator's motion, and separately regulating the correct position for each of the six degrees of freedom of the fixator. This allows minimising errors in positioning by using a string of data (the data obtained measuring the motion of the rod) rather than a single one (the position of the frame), more sensitive to digitisation errors.

At the end of this procedure the patient will be able to move the articulation being supported by a purely mechanical system, not needing further adjustments.

Notice that the system described is applicable to any articulation, and not only to the knee, even if the prototypes of the system described were developed only for this.

Also notice that six degrees of freedom necessary for each of the two portions of the fixator may belong to the fixator itself, or may be part of a different device, active (driven by the computer) or passive (driven by the operator), that should be used as a "fixation mask" to guide mounting of the real fixator while respecting the required geometry.

Such fixator, that may be made much more freely, has the only task to withstand the forces while keeping the frame of the selected mechanism at the right position with respect to the pins on the proximal side of the articulation, and the rod of said mechanism at the right position with respect to the pins on the distal side of the articulation.

Brief Description of the Drawings.

Table 1 shows a possible execution of an articulation fixator for the knee, on which a, b and c are the roto-traslational axes that supply the six degrees of freedom needed on the proximal structure. On the same table, d, e and f indicate the other six degrees of roto-translation relative to the distal structure. In between a four bar linkage is inserted. Also notice that the translational and rotational adjustment of each couple of degrees of freedom can be performed, for example, using counter nuts.

Section AA on the same table shows as, in order to uniquely position the clamp with respect to the bone patient, one of the slots on the clamp needs to present a reference hole, to be fitted by a reference pin.

Still worth of notice in the same figure the fact that one of the constraints c e d (the ones relative to the translational component) are to be set freely by the doctor, since they allow to move the four link bars along planes parallel to motion.

In particular, assuming to utilise a double four link bar for stability, constraints c e d allow positioning the four link bars on both sides of the articulation.

Also notice that the system shown in figure is only one of the infinite possible systems bearing six degrees of freedom.

For instance, in the measuring device used in the research that led to the present Patent Application (Table 2), the six degrees of freedom are all rotational, but allow as well placing the two bodies in any reciprocal position. Similarly the six degrees of freedom of both the measuring device and the two fixator's portions can be set as described in US Patent n° 5,152,280 (Table 3), or in any other configuration, as long as at least three rotational degrees are left.

Table 4 shows the distal portion of the measuring device clamped on one side to the proximal pins, and on the other to the rod of the four link bar, for adjustment of the six degrees of freedom of the proximal portion of the fixator, while Table 5 shows the measuring device hooked between the fixator end clamps, in order to set the values of the six last degrees of freedom.

As alternative to the seventeen degrees of freedom fixator one can use a six degrees of freedom system, thereby called the fixation mask, as the one shown in Table 6. In this case the system itself is positioned coupling the six degrees of freedom fixation mask to the measuring device between the clamp and the rod of the mechanism, used to reproduce the articulation movement, similarly to what shown in Table 4, then, through the computer controlled measuring device, one proceeds to the measurement of the trajectories described by the rod of the articulating mechanism.

Once the correct configuration has been obtained through sequential adjustment and locking of the six constraints (the degrees of freedom of the fixation mask), one can mount, using the mask as a guide, the structure of the real fixator.

At this point the fixation mask is removed and connected between the frame of the mechanism and the end clamp on the distal side, while the measuring device is connected between end clamps, setting this time the last six degrees of freedom on the proximal side. This is shown in Table 7.

Clearly it is also possible to use as a fixation mask a complete fixator as per Table 4.

As further alternative (Table 8), one can use a six degrees of freedom active positioning device (mounting robot) using it as substitution to the fixation mask. The active device, under computer control, will move its extremes to assume the correct relative position, allowing, as in the aforementioned case, the assembly of an external structure. In particular the fixator's extremes will have to be connected one on constraint (a) and one on constraint (f) of table 7, whereas (a), (b), and (c) are active rotating devices, while the remaining three supply the translational degrees of freedom.

Claims

1. Fixation system for articulations leaving one degree of motion, characterised by the presence of a measuring device allowing to record the instantaneous values of six parameters describing the relative motion between the bones facing an articulation. Such device is to be coupled to an electronic instrument able to detect and elaborate data (for instance a computer with data acquisition board + special purpose software), and to a device for external support of articulations.

   The articulation's external fixator is to be composed by two members connected through a mechanism leaving one degree of freedom, such as a four bars linkage or a hinge or any other mechanism, whereas each of the two members is per itself a six independent degrees of freedom system, which can be individually set, in order to allow the correct positioning of the mechanism, selected to better reproduce the patient physiological kinematism, with respect to the pins inserted into the patient's bones.

   The clamps will have to be provided by a repere slot, in order to allow uniquely positioning both the measuring device and the fixator with respect to the patient's bone structure.

2. Fixation system for articulations leaving one degree of motion, characterised by the presence of a measuring device allowing to record the instantaneous values of six parameters describing the relative motion between the bones facing an articulation. Such device is to be coupled to an electronic instrument able to detect and elaborate data (i.e. a computer with data acquisition board + special purpose software), and to a six degrees of freedom passive device.

   Such device is to be used to reproduce, regulating the values of the individual degrees of freedom under computer instruction, the correct position between the pins inserted into the patient's bony structure, and, in sequence, first the rod of the mechanism that has been selected as suitable to better reproduce the physiological motion, under control of the measuring device, and then the position of the clamp on

the other side of the articulation.

Once the correct configuration has been obtained the device is to be used as fixation mask, in order to allow the assembly of an external structure that will not have any other constraint than to correctly reproduce the end geometry of the fixation mask, while withstanding the applied forces. Also in this case the clamps will have to be provided by a repere slot, in order to allow uniquely positioning both the measuring device and the fixator with respect to the patient's bone structure.

3. Fixation system for articulations leaving one degree of motion, characterised by the presence of a measuring device allowing to record the instantaneous values of six parameters describing the relative motion between the bones facing an articulation. Such device is to be coupled to an electronic instrument able to detect and elaborate data (i.e. a computer with data acquisition board + special purpose software), and by a six degrees of freedom active device.

Such device is to be used, under direct computer control, to reproduce the correct position between the pins inserted into the patient's bony structure, and, in sequence, first the rod of the mechanism that has been selected as suitable to better reproduce the physiological motion, under control of the measuring device, and then the position of the clamp on the other side of the articulation, under direct control of the computer. Once the correct configuration has been obtained the active device (mounting robot) is to be used as fixation mask, in order to allow the assembly of an external structure that will not have any other constraint than to correctly reproduce the end geometry of the fixation mask, while withstanding the applied forces.

Also in this case the clamps will have to be provided by a repere slot, in order to allow uniquely positioning both the measuring device and the fixator with respect to the patient's bone structure

4. Fixation system for articulations leaving one degree of motion, characterised by the presence of a measuring device allowing to record the instantaneous values of six parameters describing the relative motion between the bones facing an articulation. Such device is to be coupled to an electronic instrument able to detect and elaborate data (i.e. a computer with data acquisition board + special purpose software), and by a system bearing a minimum of six and a maximum of twelve degrees of freedom used to regulate, one degree of freedom at the time, the position of the frame of a mechanism, with respect of the pins inserted into the proximal bone converging on the articulation, and the position of the rod of a mechanism, with respect of the pins inserted into the distal bone converging on the articulation.

Such mechanism is to be selected via software through analysis or synthesis methods of Applied Mechanics, based on the data obtained from the measuring device, in order to better reproduce the patient's physiological motion, and can consist in a four bar linkage, in a hinge, or in a spatial device, leaving one or two degrees of freedom to the articulation, guiding it in any event during the relative motion.

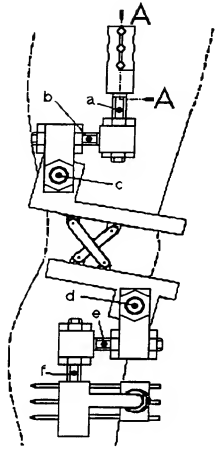


Table 1

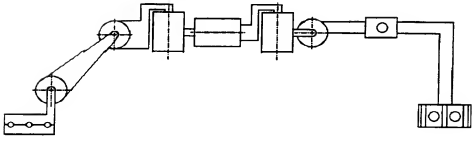


Table 2

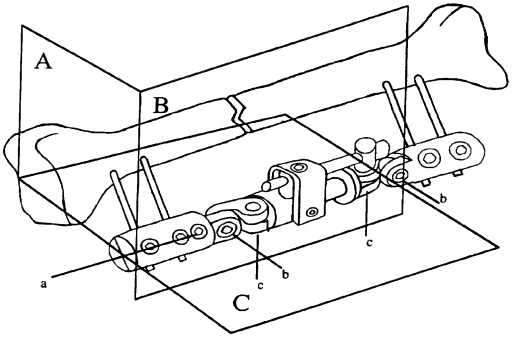


Table 3

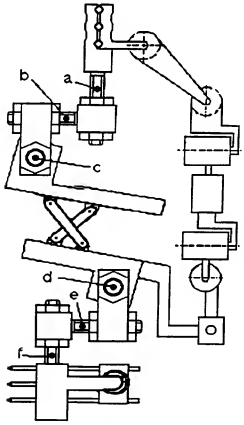


Table 4

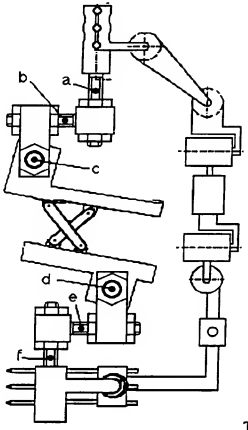


Table 5

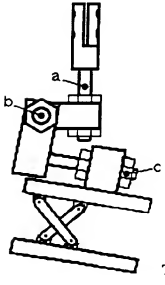


Table 6

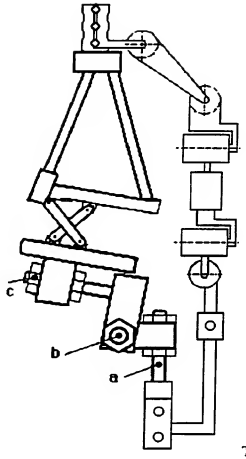


Table 7

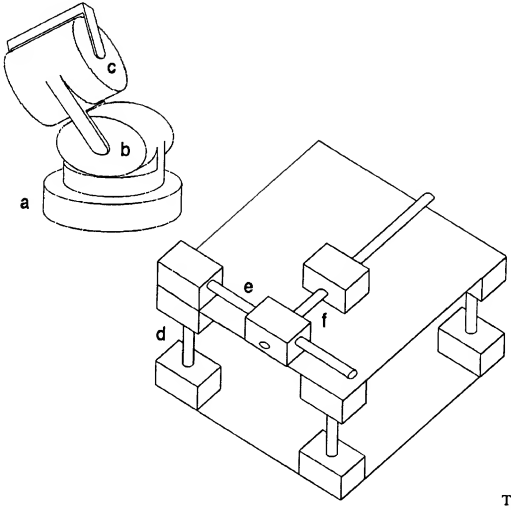


Table 8

INTERNATIONAL SEARCH REPORT

In nal Application No
PCT/IT 95/00225

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/64

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP,A,0 460 944 (SMITH & NEPHEW RICHARDS INC) 11 December 1991 see abstract; figures	1-4
A	GB,A,2 026 321 (TSNII TRAVMATOLOGII I ORTOPEDII IMENI NN PRIOROVA) 6 February 1980 see the whole document	1-4
A	WO,A,88 03395 (PROMEDA S.P.A.) 19 May 1988 see abstract	1-4

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 April 1996	22.04.96

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+ 31-70) 340-3016	Giménez Burgos, R

Form PCT ISA 210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IT 95/00225

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	CLINICAL BIOMECHANICS, vol. 9, no. 1, 1 January 1994, pages 51-59, XP000418367 GARDNER ET AL.: "THREE-DIMENSIONAL MOVEMENT AT EXTERNALLY FIXATED TIBIAL FRACTURES AND OSTEOTOMIES DURING NORMAL PATIENT FUNCTION" ---	1-4
A	WO,A,92 02184 (CAMPOPIANO) 20 February 1992 see the whole document ---	
A	GB,A,2 001 533 (GENTILE) 7 February 1979 see abstract; figures -----	

INTERNATIONAL SEARCH REPORT

In nal Application No
PCT/IT 95/00225

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0460944	11-12-91	US-A- 5100403	31-03-92
		AU-B- 650657	30-06-94
		AU-B- 7825491	12-12-91
		CA-A- 2043990	09-12-91
		JP-A- 5042174	23-02-93
		US-A- 5376091	27-12-94
		US-A- 5102411	07-04-92
GB-A-2026321	06-02-80	NONE	
WO-A-8803395	19-05-88	EP-A- 0365521	02-05-90
		JP-T- 2502608	23-08-90
WO-A-9202184	20-02-92	IT-B- 1244249	08-07-94
		AU-B- 8308891	02-03-92
		DE-D- 69101785	26-05-94
		DE-T- 69101785	04-08-94
		EP-A- 0541651	19-05-93
		ES-T- 2052389	01-07-94
		US-A- 5397322	14-03-95
GB-A-2001533	07-02-79	CH-A- 629950	28-05-82
		DE-A- 2832283	15-02-79
		FR-A- 2397826	16-02-79
		US-A- 4258708	31-03-81